

PPH Medicines and Devices Portfolio

Sara Rushwan, Concept Foundation, MHS Caucus, 17 October 2023



Country Support

Project title:

Accelerating access to essential medicines to reduce PPH morbidity and mortality

Policy updates:
National guidelines,
EMLs and
EPHS



Developing
clinical
protocols and
job aids



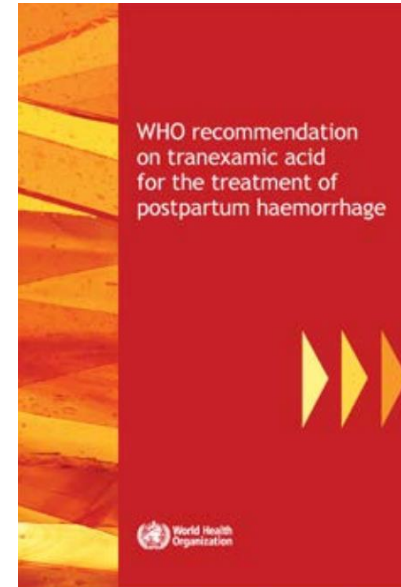
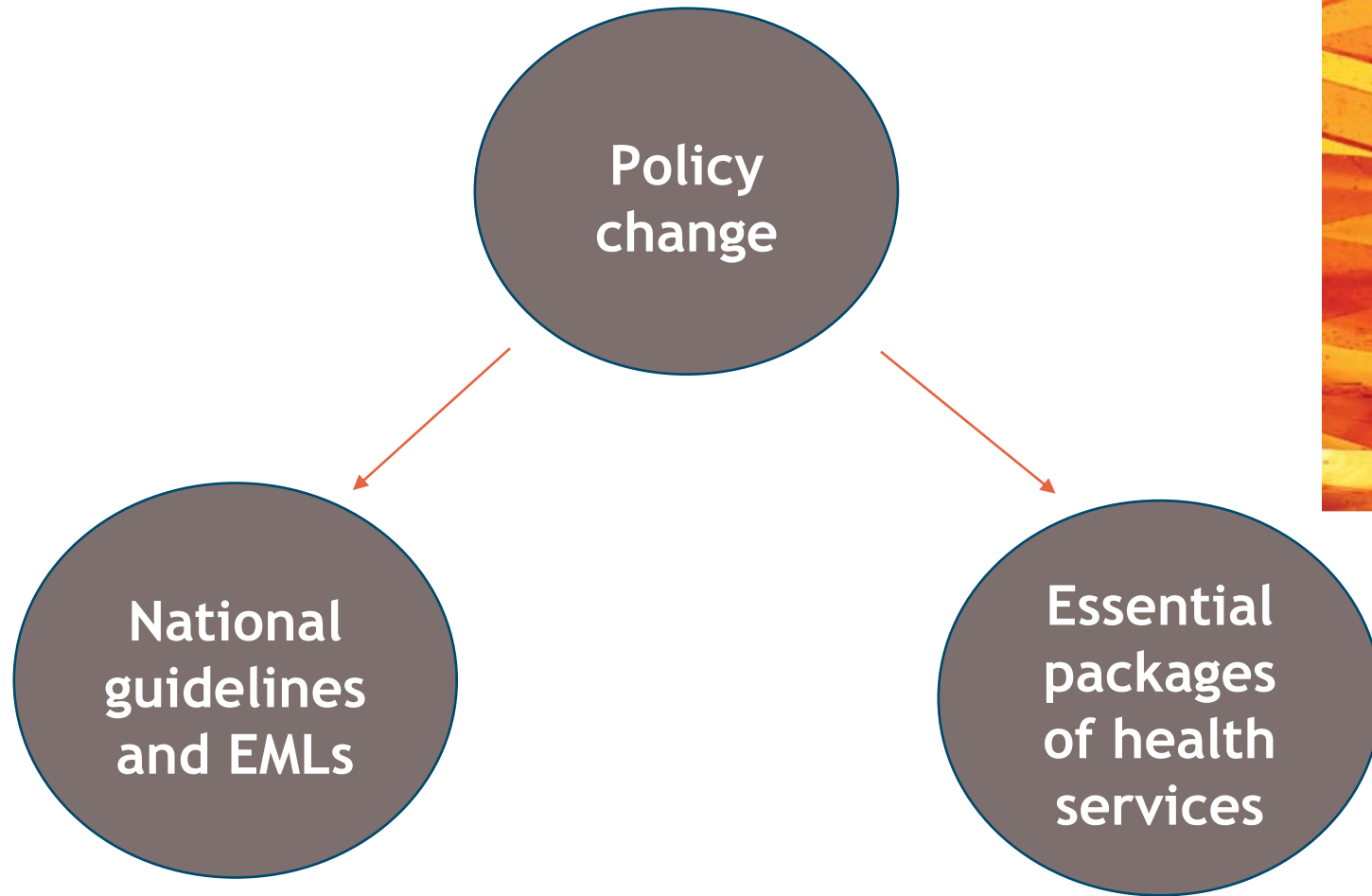
Implementation
pilots on safe
and
appropriate use



EML - Essential Medicines List

EPHS - Essential Packages of Health Services

Policy change objective: Update national policies to include HSC and TXA



2017



Project Countries

15 sub-Saharan African countries with a high burden of PPH

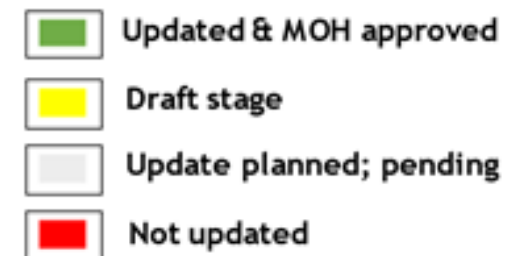
East African Community	Economic Community of West African States
<ol style="list-style-type: none">1. Burundi2. DRC3. Ethiopia4. Rwanda5. South Sudan6. Tanzania7. Uganda8. Zanzibar	<ol style="list-style-type: none">1. Burkina Faso2. Ghana3. Ivory Coast4. Liberia5. Mali6. Sierra Leone7. Senegal

POLICY OUTPUTS

10 countries updated their national guideline and/or EML to include HSC and TXA

Status of inclusion of heat-stable carbetocin and tranexamic acid into national guidelines and EMLs:

Country ¹	National guideline status	National EML status
1. Burkina Faso	Updated & MOH approved	Updated & MOH approved
2. DRC	Updated & MOH approved	Updated & MOH approved
2. Ethiopia	Updated & MOH approved	Update planned; pending
4. Ghana	Updated & MOH approved	Updated & MOH approved
5. Liberia	Updated & MOH approved	Draft stage
6. Rwanda	Updated & MOH approved	Updated & MOH approved
7. Senegal	Draft stage	Draft stage
8. South Sudan	Draft stage	Updated & MOH approved
9. Sierra Leone	Updated & MOH approved	Updated & MOH approved
10. Ivory Coast	Not updated	Updated & MOH approved
11. Uganda	Updated & MOH approved	Updated & MOH approved



¹Burundi, Mali, Tanzania, and Zanzibar did not progress in revising their national guideline and EML within the timeframe due to a range of contextual factors, including the recent update of national policies



Volume 158, Issue S1

Special Issue: Improving access to essential medicines to reduce postpartum hemorrhage morbidity and mortality

Pages: 1-55

June 2022

Issue Edited by: Charles Ameh, Fernando Althabe

DOI: 10.1002/ijgo.14269

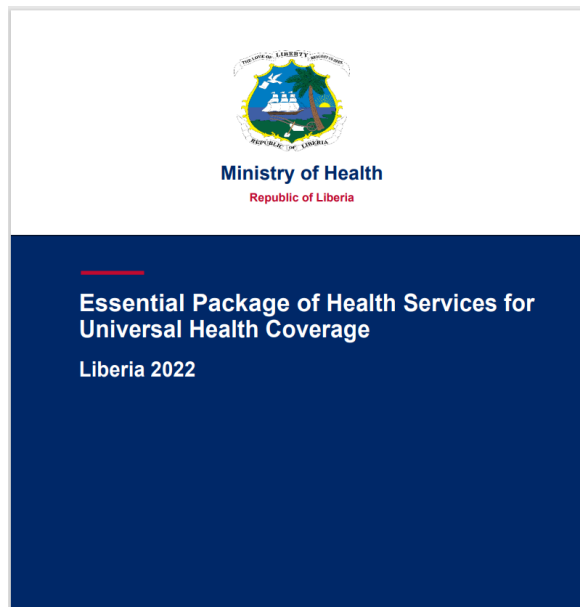
SUPPLEMENT ARTICLE



Challenges in updating national guidelines and essential medicines lists in Sub-Saharan African countries to include WHO-recommended postpartum hemorrhage medicines

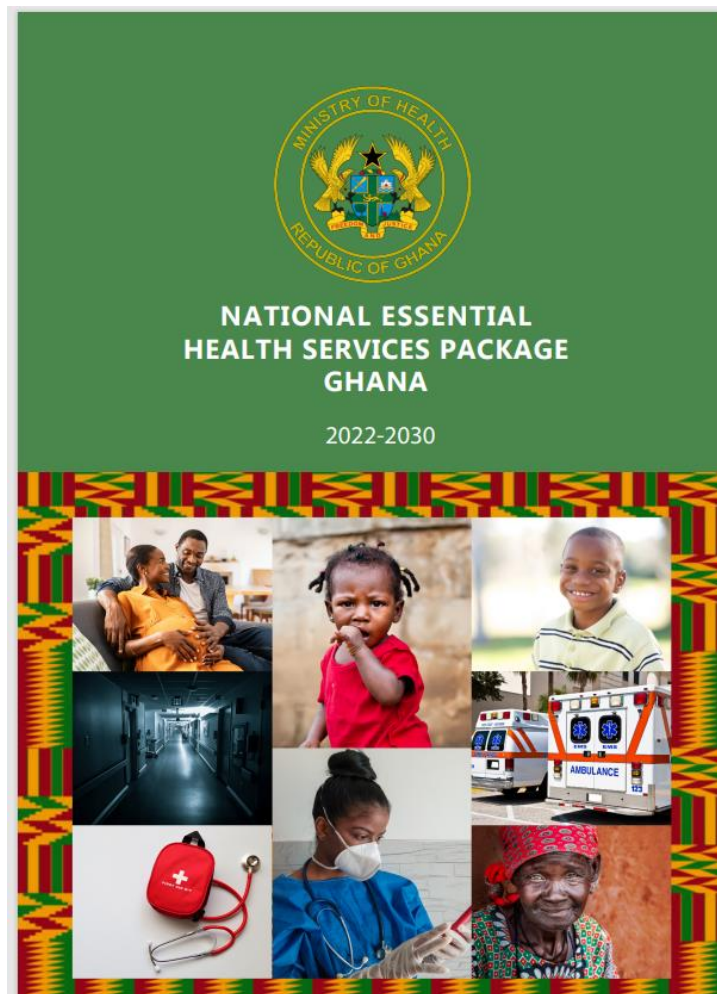
Joyce Ng'ang'a¹ | Tabeth Chitimbe¹ | Rosemary Mburu¹ | Sara Rushwan² |
David Ntirushwa³ | Lester Chinery² | A. Metin Gülmezoglu²

Liberia

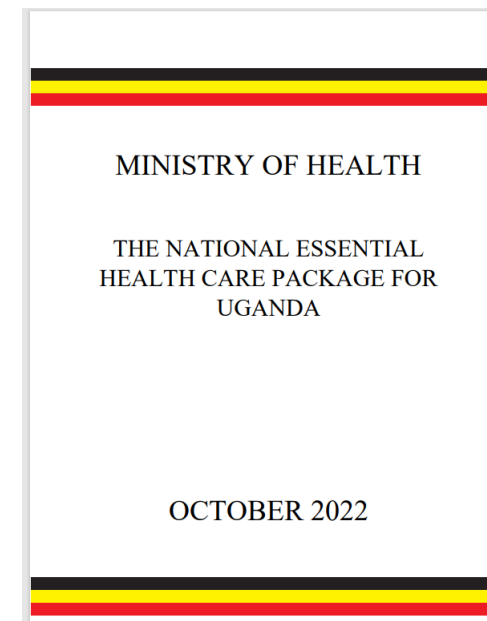


Updated Essential Packages of Health Services

Ghana



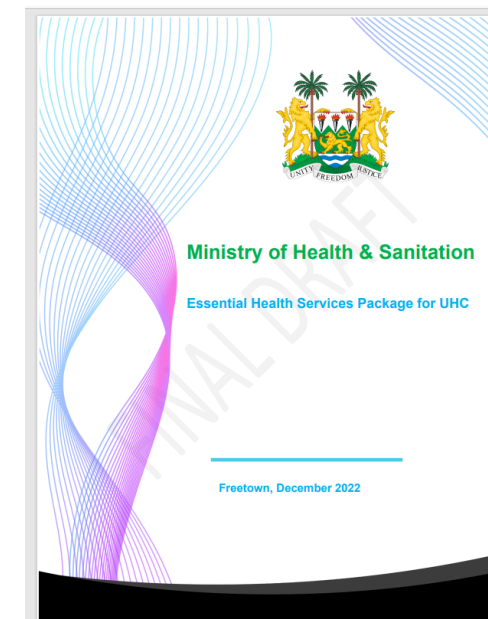
Uganda



DRC



Sierra Leone



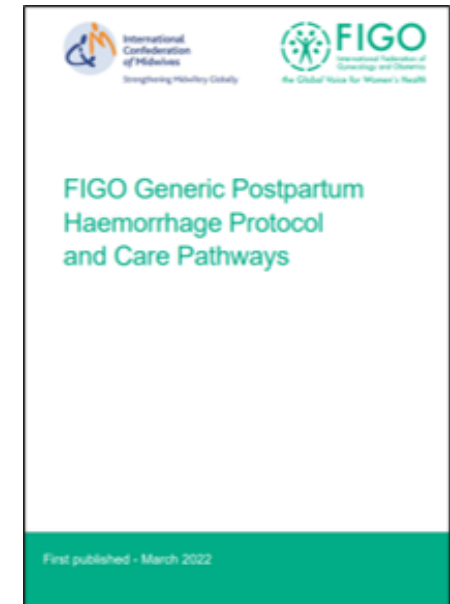
Key learnings from policy change and clinical protocol development

- ❖ Political will and civil society engagement are **key gateways** to policy change
- ❖ Convening **expert working groups** that include representation from professional associations is integral to clinical protocol development and operationalization
- ❖ Success is sustainable when efforts are **locally-driven**
- ❖ There is added value to operationalizing global recommendations at the national level when OBGYN and midwifery associations work in **partnership**

Developing clinical PPH protocols and job aids

Outputs:

- 2 published joint FIGO and ICM statements on PPH prevention and treatment
- 8 Expert Working Groups
- **Published** generic PPH prevention and management protocol
- 5 newly developed national clinical PPH protocols
- 2 revised national PPH clinical protocols
- 41 Job Aids
- 1 IJGO PPH-specific Supplement



HSC and TXA implementation pilots

Overall Study Objectives:

- 1) To assess safe and appropriate use of HSC for PPH prevention, and TXA for PPH treatment, and 2) their integration into standard care.

Study start and end date

1st May - 31st December 2022

Study Countries

Burkina Faso

Ethiopia

Ghana

Sierra Leone

Uganda

Study Design

BASELINE

Baseline data collection to from 1st May to 30th June 2022



TRAINING

Facility-level training of trainers and staff of all study facilities



IMPLEMENTATION

- Introduction of HSC and TXA into all study facilities (*medicines were supplied by IDA Foundation*)
- Post-intervention data collection for a 2-month period
- Principal investigators/assigned seniors carried out weekly monitoring and monthly support supervision of all study facilities

Country	No. of deliveries captured in the study	No. of healthcare providers sampled for qualitative research	No. of BEmONCs	No. of CEmONCs	No. of healthcare providers trained on using HSC and TXA
Burkina Faso	3617	30	2	2	102
Ethiopia	3840	28	2	2	226
Ghana	4332	40	2	2	237
Sierra Leone	3361	26	2	2	175
Uganda	9966	16	1	2	221
TOTAL	25116	140	9	10	961

Quantitative results summary

- HSC was the **most used uterotonic** for PPH prevention in both BEmONCs and CEmONCs during implementation
- HSC was administered in combination with other uterotonics to **3.1%** of women in Ghana, **0.5%** of women in Burkina Faso and Uganda, and **0.1%** in Sierra Leone (all in CEmONCs)
- Ampoule counts showed that HSC **was not used** for labour induction and augmentation at all study facilities
- During implementation, times from delivery to TXA administration for PPH treatment in all study facilities were **within the 180-minute** WHO-recommended treatment time
- **75%** of healthcare providers in all study countries visually estimate blood loss (N = 140)

Qualitative results summary

Healthcare providers overall did not have major hesitations over use of HSC and/or TXA

THEME	SUB-THEME	EXAMPLE QUOTE/S	OCCURRENCE IN COUNTRIES	STUDY PHASE
Hesitations using HSC/ TXA				
	<i>Reasons for hesitations</i>	"Lack of knowledge about the products" "We don't have the drugs and don't know how to use them"	All countries	Baseline
		"Fear about the effectiveness of HSC"	Ethiopia	Baseline
		"Lack of training and availability of the drugs"	All countries	Baseline + Implementation
		"Deepening knowledge of thermostable carbetocin"	Burkina Faso	Implementation
		"Further training on use of TXA because the administration time is long, the product requires great caution"	Burkina Faso	Implementation

Learnings from the implementation pilots

- Healthcare providers had favorable opinions about both medications in terms of ease of use (no cold chain required) and perceived effectiveness at reducing PPH with no reported adverse events
- HSC and TXA can be feasibly integrated into routine care but there is a need for a holistic approach to PPH training with supportive supervision
- Impact of introducing HSC and TXA on established practices (such as combining oxytocin and misoprostol for PPH prevention) should be monitored
- Health information systems need to be improved for reliable record capture of timing of administration

Supplement on implementation research from 9 LMIC to be published in Q1 2024

Scope of supplement: Feasibility, acceptability and appropriate use of two WHO-recommended PPH medicines: heat-stable carbetocin and tranexamic acid









Research & Innovation



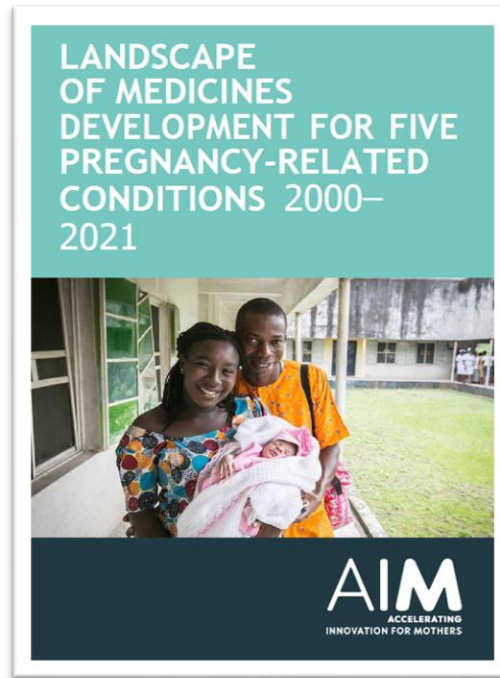
Project 2: Accelerating Innovation for Mothers (AIM)

<p>ACTIVITY 1</p> <p>Clinical trial capacity assessment and strengthening for an LMIC clinical trial network</p>  <p>FIND OUT MORE +</p>	<p>ACTIVITY 2</p> <p>Historical funding analysis of the R&D landscape for Maternal Health medicines</p>  <p>FIND OUT MORE +</p>	<p>ACTIVITY 3</p> <p>Maternal Health Pipeline</p>  <p>FIND OUT MORE +</p>
<p>ACTIVITY 4</p> <p>Target Product Profiles</p>  <p>FIND OUT MORE +</p>	<p>ACTIVITY 5</p> <p>Systematic and Scoping reviews</p>  <p>FIND OUT MORE +</p>	<p>ACTIVITY 6</p> <p>AIM-Gender</p>  <p>FIND OUT MORE +</p>

Impact



Stakeholder analysis



Maternal Health Pipeline

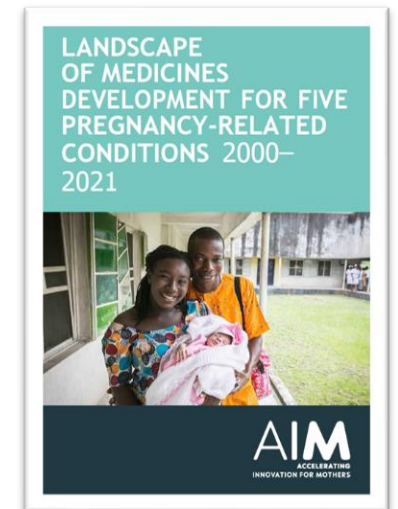


TPPs

Maternal Health Pipeline

Our mapping of the Maternal Health Pipeline 2000-2023 generated:

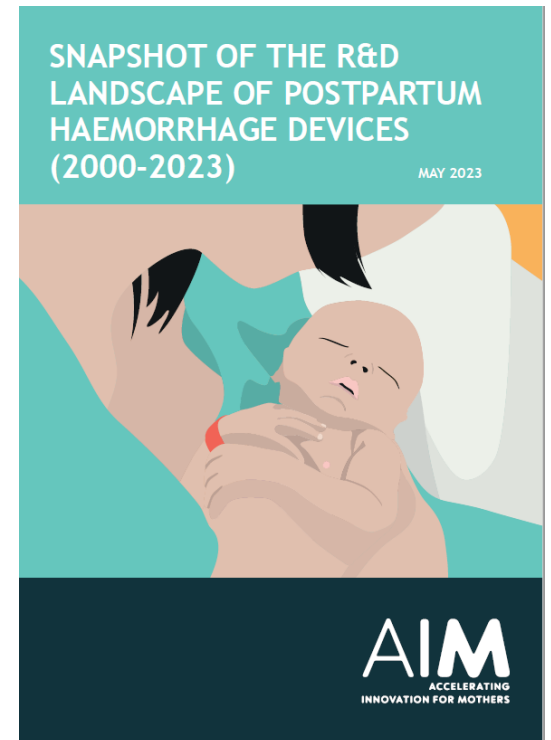
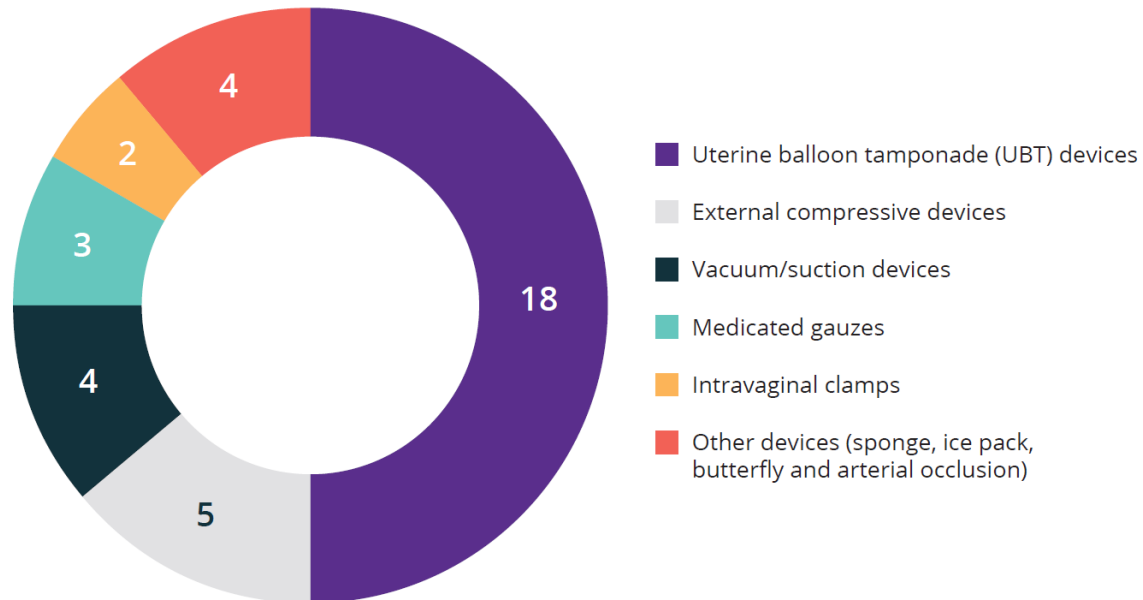
- 444 drugs candidates for five main pregnancy conditions
 - 36 devices for PPH
- 216 diagnostics for PE/E, PTL/B and IUGR
- 70 medicines for maternal anaemia



Maternal Health Pipeline

PPH device pipeline 2000 - 2023

- **36 devices** were identified as in use or investigated for PPH between 2000 and 2023
- Balloons dominate, but **novel approaches are emerging**
- Repurposed and **improvised devices** are the norm



TXA research and market shaping activities

We have a series of ongoing TXA research activities designed to establish the availability and quality of TXA products in high-burden LMIC:

- Quality studies of TXA and oxytocin – *published and ongoing*
- TXA compatibility studies – *published and ongoing*
- TXA manufacturer landscaping
- Regulatory status and availability in high-burden countries
- Assessments of TXA innovations

Project 3: Uterotonic Medication Quality: Contributions Toward Universal Health Coverage

- Key aims of the study are to:
 - ❖ Highlight the importance of safeguarding uterotonic medication quality in low- and middle-income countries
 - ❖ Generate evidence to drive policy change through demonstrating both the **health** and **economic** impact that substandard uterotonics could have

Key findings from Ghana and Nigeria models:

- Substandard uterotonic use contributes to **\$89 million in total costs of care** annually in **Nigeria**
- Substandard uterotonic use contributes to **\$18.8 million in total costs of care** annually in **Ghana**

Resources:

Access-PPH project: <https://www.conceptfoundation.org/pph/>

AIM project: <https://www.conceptfoundation.org/accelerating-innovation-for-mothers/>

IJGO supplement:

<https://obgyn.onlinelibrary.wiley.com/toc/18793479/2022/158/S1>

UMQ project: <https://www.conceptfoundation.org/pph/quality-of-pph-medicines/quality-and-universal-health-coverage/>

THANK YOU!

<https://www.conceptfoundation.org/>

s.rushwan@conceptfoundation.org

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